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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,721	05/02/2001	John Charles Brennand	1991-196	3814

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,721	Applicant(s) BRENNAND ET AL.	
	Examiner Michael Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action/attach* .

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences in Tables 1 and 2, pages 14-15, do not have SEQ ID NOs**. Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a method of screening agonists of GPR22 capable of being an appetite control agent, classified in unknown class and subclass.

II. Claims 1 and 2, drawn to a method of screening antagonists of GPR22 capable of being an appetite control agent, classified in unknown class and subclass.

III. Claims 3 and 5, drawn to a method of using an agonist of GPR22 as an appetite control agent, classified in unknown class and subclass.

IV. Claims 4 and 5, drawn to a method of using an antagonist of GPR22 as an appetite control agent, classified in unknown class and subclass.

V. Claim 6, drawn to an antisense oligonucleotide, classified in class 536, subclass 24.5.

VI. Claims 7 and 9, drawn to a dominant negative mutant of GPR22, classified in unknown class and subclass.

VII. Claims 8 and 9, drawn to drawn to a dominant positive mutant of GPR22, classified in unknown class and subclass.

VIII. Claims 10 and 11, drawn to a transgenic non-human animal in which GPR22 has been deleted, classified in class 800, subclass 8.

IX. Claim 12, drawn to an antibody against GPR22, classified in class 530, subclass 387.1.

Groups I and II are patentably distinct because methods of detecting agonists and antagonists of GPR22 require materially distinct steps, protocols and reagents. The method of detecting agonists is used to detect molecules that increase the function of GPR22 while the method of detecting antagonists is used to detect molecules that decrease the function of GPR22. The method of detecting agonists is not required for the method of detecting antagonists and the method of detecting antagonists is not required for the method of detecting agonists.

Groups I and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using.

Groups I and IV are patentably distinct because the methods of detecting agonists of GPR22 require materially distinct steps, protocols and reagents than methods of using antagonist of GPR22 as an appetite control agent. The method of detecting agonists is used to detect molecules that increase the function of GPR22 while the method of using antagonists as an appetite control agent requires a decrease in function of GPR22. The method of detecting agonists is not required for the method of using an antagonist as an appetite control agent and the method of using an antagonist as an appetite control agent is not required for the method of detecting agonists.

Groups I and V are patentably distinct because methods of detecting agonists of GPR22 can be used to identify appetite control agents while antisense can be used as a probe or to prevent GPR22 expression. The protocols and reagents required for the method of detecting agonists are materially distinct and separate than those required for antisense. The method of detecting agonists does not require antisense and antisense does not require the method of detecting agonists.

Groups I and VI are patentably distinct because methods of detecting agonists can be used to identify appetite control agents while dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the

method of detecting agonists are materially distinct and separate than those required for a dominant negative mutant of GPR22. The method of detecting agonists is not required for the dominant negative mutants of GPR22 and the dominant negative mutants of GPR22 are not required for the method of detecting agonists.

Groups I and VII are patentably distinct because methods of detecting agonists can be used to identify appetite control agents while dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of detecting agonists are materially distinct and separate than those required for a dominant positive mutant of GPR22. The method of detecting agonists is not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the method of detecting agonists.

Groups I and VIII are patentably distinct because methods of detecting agonists can be used to identify appetite control agents while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for the method of detecting agonists are materially distinct and separate than those required for transgenics. The method of detecting agonists is not required for the transgenics and the transgenics are not required for the method of detecting agonists.

Groups I and IX are patentably distinct because methods of detecting agonists can be used to identify appetite control agents while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for the method of detecting

agonists are materially distinct and separate than those required for using antibodies to isolate protein or to detect eating disorders. The method of detecting agonists is not required for the antibodies and the antibodies are not required for the method of detecting agonists.

Groups II and III are patentably distinct because methods of detecting antagonists of GPR22 and methods of using agonists of GPR22 as an appetite control agent require materially distinct steps, protocols and reagents. The method of detecting antagonists is used to detect molecules that increase the function of GPR22 while the method of using agonists as appetite control agents requires that the function of GPR22 is increased. The method of detecting antagonists is not required for the method of using agonists as appetite control agents and the method of using agonists as appetite control agents is not required for the method of detecting antagonists.

Groups II and IV are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using.

Groups II and V are patentably distinct because methods of detecting antagonists of GPR22 can be used to identify appetite control agents while antisense can be used as a probe or to prevent GPR22 expression. The protocols and reagents required for the method of detecting antagonists are materially distinct and separate than those required for antisense. The method of detecting antagonists does not require antisense and antisense does not require the method of detecting antagonists.

Groups II and VI are patentably distinct because methods of detecting antagonists can be used to identify appetite control agents while dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of detecting antagonists are materially distinct and separate than those required for a dominant negative mutant of GPR22. The method of detecting antagonists is not required for the dominant negative mutants of GPR22 and the dominant negative mutants of GPR22 are not required for the method of detecting antagonists.

Groups II and VII are patentably distinct because methods of detecting antagonists can be used to identify appetite control agents while dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of detecting antagonists are materially distinct and separate than those required for a dominant positive mutant of GPR22. The method of detecting antagonists is not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the method of detecting antagonists.

Groups II and VIII are patentably distinct because methods of detecting antagonists can be used to identify appetite control agents while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for the method of detecting antagonists are materially distinct and separate than those required for transgenics. The method of detecting antagonists is not required for the transgenics and the transgenics are not required for the method of detecting antagonists.

Groups II and IX are patentably distinct because methods of detecting antagonists can be used to identify appetite control agents while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for the method of detecting antagonists are materially distinct and separate than those required for using antibodies to isolate protein or to detect eating disorders. The method of detecting antagonists is not required for the antibodies and the antibodies are not required for the method of detecting antagonists.

Groups III and IV are patentably distinct because methods of using an agonist of GPR22 as an appetite control agent cause a increase in function of GPR22 while methods of using an antagonist of GPR22 as an appetite control agent causes a decrease in function of GPR22. The protocols and reagents required to decrease and increase the function of GPR22 are materially distinct and separate. A method of increasing the function of GPR22 using an agonist is not required for a method of decreasing the function of GPR22 using an antagonist and vice versa.

Groups III and V are patentably distinct because methods of using agonists of GPR22 can be as an appetite control agent while antisense can be used as a probe or to prevent GPR22 expression. The protocols and reagents required for the method of using agonists as appetite control agents are materially distinct and separate than those required for antisense. The method of using agonists as appetite control agents does not require antisense and antisense does not require the method of using agonists as appetite control agents.

Groups III and VI are patentably distinct because methods of using agonists can be as an appetite control agents while dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of using agonists as appetite control agents are materially distinct and separate than those required for a dominant negative mutant of GPR22. The method of using agonists as an appetite control agent is not required for the dominant negative mutants of GPR22 and the dominant negative mutants of GPR22 are not required for the method of using agonists as an appetite control agent.

Groups III and VII are patentably distinct because methods of using agonists can be as an appetite control agent while dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of using agonists as appetite control agents are materially distinct and separate than those required for a dominant positive mutant of GPR22. The method of using an agonist as appetite control agent is not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the method of using agonists as appetite control agents.

Groups III and VIII are patentably distinct because methods of using agonists can be as an appetite control agent while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for the method of using agonists as appetite control agents are materially distinct and separate than those required for transgenics. The method of using an agonist as appetite control agent is not required for the

transgenics and the transgenics are not required for the method of using an agonist as appetite control agent.

Groups III and IX are patentably distinct because methods of using an agonist can be as an appetite control agent while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for the method of using an agonist as appetite control agent are materially distinct and separate than those required for using antibodies to isolate protein or to detect eating disorders. The method of using an agonist as appetite control agent is not required for the antibodies and the antibodies are not required for the method of using an agonist as appetite control agent.

Groups IV and V are patentably distinct because methods of using antagonists of GPR22 can be as an appetite control agent while antisense can be used as a probe or to prevent GPR22 expression. The protocols and reagents required for the method of using antagonists as appetite control agents are materially distinct and separate than those required for antisense. The method of using antagonists as appetite control agents does not require antisense and antisense does not require the method of using antagonists as appetite control agents.

Groups IV and VI are patentably distinct because methods of using antagonists can be as an appetite control agents while dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of using antagonists as appetite control agents are materially distinct and separate than those required for a dominant negative mutant of GPR22. The method of using antagonists as an

appetite control agent is not required for the dominant negative mutants of GPR22 and the dominant negative mutants of GPR22 are not required for the method of using antagonists as an appetite control agent.

Groups IV and VII are patentably distinct because methods of using antagonists can be as as an appetite control agent while dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for the method of using antagonists as appetite control agents are materially distinct and separate than those required for a dominant positive mutant of GPR22. The method of using an antagonist as appetite control agent is not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the method of using antagonists as appetite control agents.

Groups IV and VIII are patentably distinct because methods of using antagonists can be as an appetite control agent while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for the method of using antagonists as appetite control agents are materially distinct and separate than those required for transgenics. The method of using antagonists as appetite control agents is not required for the transgenics and the transgenics are not required for the method of using an antagonist as appetite control agent.

Groups IV and IX are patentably distinct because methods of using an antagonist can be as an appetite control agent while antibodies against GPR22 can be used to isolate GPR22 or to

detect eating disorders. The protocols and reagents required for the method of using an antagonist as appetite control agent are materially distinct and separate than those required for using antibodies to isolate protein or to detect eating disorders. The method of using an antagonist as appetite control agentis not required for the antibodies and the antibodies are not required for the method of using an antagonist as appetite control agent.

Groups V and VI are patentably distinct because antisense can be used as a probe or to prevent GPR22 expression while dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for antisense are materially distinct and separate than those required for a dominant negative mutant of GPR22. Antisense is not required for the dominant negative mutants of GPR22 and the dominant negative mutants of GPR22 are not required for the antisense.

Groups V and VII are patentably distinct because antisense can be used as a probe or to prevent GPR22 expression while dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite. The protocols and reagents required for antisense are materially distinct and separate than those required for a dominant positive mutant of GPR22. Antisense is not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the antisense.

Groups V and VIII are patentably distinct because antisense can be used as a probe or to prevent GPR22 expression while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for

antisense are materially distinct and separate than those required for transgenics. Antisense is not required for the transgenics and the transgenics are not required for the antisense.

Groups V and IX are patentably distinct because antisense can be used as a probe or to prevent GPR22 expression while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for making or using the antisense are materially distinct and separate than those required for antibodies. Antisense is not required for the antibodies and the antibodies are not required for the antisense.

Groups VI and VII are patentably distinct because dominant negative mutants of GPR22 have decreased GPR22 function while dominant positive mutants of GPR22 have enhanced GPR22 function. The protocols and reagents required for using GPR22 mutants having decrease function are materially distinct and separate than those required for using GPR22 mutants having increased function. In addition, the search for dominant negative and positive mutants of GPR22 would be different because dominant negative mutants of GPR22 would have a different structure than dominant positive mutants. Dominant negative mutants of GPR22 are not required for the dominant positive mutants of GPR22 and the dominant positive mutants of GPR22 are not required for the dominant negative mutants.

Groups VI and VIII are patentably distinct because dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for dominant negative mutants of GPR22 are materially distinct

and separate than those required for transgenics. Dominant negative mutants of GPR22 are not required for the transgenics and the transgenics are not required for the dominant negative mutants.

Groups VI and IX are patentably distinct because dominant negative mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for dominant negative mutants of GPR22 are materially distinct and separate than those required for antibodies. Dominant negative mutants of GPR22 are not required for the antibodies and the antibodies are not required for the dominant negative mutants of GPR22.

Groups VII and VIII are patentably distinct because dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite *in vitro* while transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo*. The protocols and reagents required for using dominant positive mutants of GPR22 to determine the role of GPR22 are materially distinct and separate than those required for transgenics. Dominant positive mutants of GPR22 are not required for the transgenics and the transgenics are not required for the dominant positive mutants. The burden required to search both groups together would be undue.

Groups VII and IX are patentably distinct because dominant positive mutants of GPR22 can be used to evaluate the role of GPR22 in the control of appetite while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents

required for dominant positive mutants of GPR22 are materially distinct and separate than those required for antibodies. Dominant positive mutants of GPR22 are not required for the antibodies and the antibodies are not required for the dominant positive mutants of GPR22.

Groups VIII and IX are patentably distinct because transgenics having GPR22 deleted can be used to evaluate the role of GPR22 in the control of appetite *in vivo* while antibodies against GPR22 can be used to isolate GPR22 or to detect eating disorders. The protocols and reagents required for transgenics are materially distinct and separate than those required for antibodies. The transgenics are not required for the antibodies and the antibodies are not required for the transgenics.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER

Application No.: 09/845721

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: The sequences in Tables 1 and 2, pg 14-15, do not have SEQ ID NOs.

If necessary, applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE